REMARKS

Applicants have carefully considered the Examiner's comments in the outstanding Office Action as well as the prior art document noted therein. For the following reasons, the pending claims are allowable.

Basel et al. U.S. Patent No. 4,962,537, the basis of the prior art based rejections of the pending claims, is quite unlike the claimed structure. Basel describes a conventional hearing aid structure with material 23 forming a hard rigid exterior shell, when cured, which surrounds a deformable plastic member 6. The deformable member 6 contains and carries hearing aid components such as receiver 9, amplifier system 10, battery 12 and control stage 13. The deformable plastic member 6 (having 2 half sections 14, 15), for example, a co-vulcanized silicon rubber (Col. 2, line 67-Col. 3. line 2) is not attached to the exterior skin 22. Indeed, the exterior skin 22 is intended to be removed from the hardened material 23 as Basel et al. explains:

> "After the plastic member 6 has been adapted to the shape of the auditory canal, the sleeve 22 is filled with otoplastic material 23 via filling openings 22' until the sleeve 22 presses against the walls of the auditory canal. The otoplastic material 23, which is initially fluid, is subsequently hardened using known processes, for example, light curing process if the material contains a photo initiator, or a chemical curing if the material consists of two mixed components. As soon as the otoplastic material 23 has completely hardened, the hearing aid 8 is removed from the auditory canal so that the sleeve 22 can be removed." (Col. 3, lines 10-22 Basel et al., emphasis added)

As the above makes clear, exterior skin 22 is never attached in any way to structure 6. The resultant hearing aid has the rigid exterior shell 23 which in turn surrounds the internal compliant structure 6. Shell 23 does not change shape or internal volume for any reason. Hence, when the Basel et al. structure is inserted into the user's ear canal, the material 23 never changes shape or form, due to the fact that it had previously been cured and is rigid.

For all of the above reasons, none of pending claims 21-27, 29, 30, 32-34, 104-110, 112-113, and 115-117 are anticipated by Basel et al. For the same reasons, none of claims 28, 31, 111 and 114 are obvious and unpatentable in view of Basel et al.

In rejecting claims 21, 22 and 104, 105, the Examiner stated that Basel et al.:

> "disclose a hearing aid, comprising: a deformable skin (22) bounding an internal region (23); and at least one spine (15) extending axially along an interior surface of the skin, which is attached thereto sufficiently so as to provide insertion rigidity when inserted into the user's ear canal (Fig. 2) as claimed." (Page 5, Numbered Section 11 of Office Action).

Anticipation requires that the alleged anticipating structure exhibit all of the limitations of the claim that is said to be anticipated arranged exactly as claimed. The structure of Fig. 2 of Basel et al. does not pass this test. Hence there can be no anticipation.

As made clear from the above quotation from Basel et al., there is absolutely no connection between exterior skin 22 and the interior deformable member 15. The skin 22 is intended to be removed from the exterior periphery of the hardened material 23. Hence, the Examiner's reference above to "which is attached thereto sufficiently so as to provide insertion rigidity when inserted into the user's ear canal" is simply not met in Basel et al.

The fact that a user might be able to insert the hearing aid of Fig. 2 of Basel et al., including the external skin 22, into his or her ear canal does not overcome the fact that exterior skin 22 is simply not in any way "attached" as claimed to interior member 15. In fact, a hearing aid user would run the risk of the structure of Fig. 2, upon being inserted into that user's ear canal, leaving the exterior skin 22 in the ear canal when the remainder of the hearing aid surrounded by the rigid body 23 is removed from the user's ear canal. Hence, for at least the above reasons, none of the claims rejected as anticipated, are in fact anticipated by Basel et al.

In addition to the above reasons, the rejection of claims 23, 24, 106 and 107 as anticipated by Basel et al. is defective and should be withdrawn. None of the skin 22, nor element 15 of Basel et al. will experience any distortion as the user inserts that structure into his or her ear canal. The hardened exterior shell 23 prevents any such distortion. While the Examiner has rejected claims 23 and 106 as anticipated by Basel et al., the Office Action completely fails to set forth structure or features of Basel et al. that correspond to either claim 23 or 106. Hence, each of those claims is also allowable and not anticipated by Basel et al.

The rejection as anticipated of claims 24 and 107 by Basel et al. is also defective. In articulating a rejection of claims 24 and 107, the Examiner merely stated:

> "Basel et al. further disclose the hearing aid, wherein the hearing aid further includes a sound conductive tube (Fig. 3) as claimed." (page 5, paragraph 11, Office Action).

The only sound conductive tube shown in Fig. 3 of Basel et al. is audio output port 17.1 which is not attached at all to skin 22 of Fig. 2 of Basel et al. In fact, skin 22 is not used in the fabrication of the hearing aid of Fig. 3 of Basel et al. In this regard, Basel et al. state:

> "The sleeve 22 may be omitted if the final shaping is under taken in a negative or an ear impression. The sleeve 22 may also be omitted if the final shaping is undertaken directly in the ear of the user, if a sufficiently viscous otoplastic material is used, so that the material cannot flow into the inner auditory canal. Such an alternative is shown in Fig. 3, wherein the hearing aid 8.1 shown in longitudinal section, is seated in the auditory canal 25 of a patient without a sleeve, and is surrounded by otoplastic material 23.1 on all sides." (Col. 3, lines 25-34, Basel et al.).

The audio output tube 17.1 of Fig. 3 of Basel et al. is completely separate from the sound entry channel 16.1 which is coupled to the microphone 11.1. Two such completely isolated paths do not correspond to the claimed "vent tube that is attached to the skin substantially along its length." (claims 24 and 107).

In rejecting claims 25-27, 32, 33, 108-110, 115 and 116, the Examiner merely stated that:

"Basel et al. further disclose the hearing aid, wherein a deformable matrix (23) applying [sic] expansive forces to the skin." (page 5, paragraph 11 of Office Action).

The above statement is clearly incorrect and inaccurate. The material 23, Fig. 2 of Basel et al. or 23.1, Fig. 3 of Basel et al. is cured and becomes a rigid non-deformable material. Basel et al. require that the material 23or 23.1 completely fill the spaces between the deformable member 6 and the user's ear canal and be cured so as to become rigid therein. In this regard, Basel et al. state:

"The components in the plastic compound, thus shaped, are then cast in a conventional otoplastic material, which precisely conforms to the shape of the auditory canal so that the remainder of the volume between the roughly shaped components in the flexible plastic component is filled with the otoplastic material, which is then cured to harden into a shape exactly conforming to the ear canal." (Col. 1, lines 39-47 Basel et al.)

The above describes Basel et al.'s process of creating a rigid shell 23, 23.1 which exactly conforms to the shape of the wearer's ear canal in one state. It is only in that one state that the member 23, 23.1 completely seals adjacent to the user's ear canal. Unlike the structures of claims 25-27, 32, 33, 108-110, 115, and 116, the rigid shell 23, 23.1, does not change shape, or vary in cross section or internal volume as the shape of the user's ear canal changes. Rather, the shape of the ear canal changes around the exterior periphery of the rigid material 23, 23.1, which is quite unlike the claimed structure.

The rejection of claims 30 and 113 as anticipated by Basel et al. is also defective and should be withdrawn. Claim 30 is dependent on claim 29 and includes the limitations of claim 29 therein. Thus, claim 30 requires:

"an audio output transducer in the internal region wherein the transducer is surrounded, at least in part, by a compressible matrix. (claim 29) ... "wherein the matrix pre-loads the skin with outwardly directed expansive forces" (claim 30)

In rejecting claims 30 and 113, the Examiner merely stated relative to Basel et al. that:

> "an audio output transducer (9) surrounded, at least in part, by a compressible matrix (Figs. 2-3) as claimed." (page 5, Numbered Section 11 of Office Action)

The compressible material 6 of Basel et al. which surrounds output transducer 9 does not correspond to the structure of either claim 30 or 113. That material is contained within the deformable member 6 (sections 14, 15), which is inserted into the user's ear canal prior to the material 23 being used to fill the spaces between the member 6 and the user's ear canal or the skin 22. The compressible matrix 14, 15 which surrounds the output transducer 9 of Basel et al. does not apply any expansive forces to skin 22 at any time as claimed. It is the material 23 which is injected between the member 6 and the skin 22 in Basel et al. which fills the space between the member 6 and the user's ear canal. If there are any "outwardly directed expansive forces" as claimed, they are not provided by the material 6 which surrounds the output transducer 9. Hence, for these additional reasons neither claim 30 nor 113 are anticipated by Basel et al.

In rejecting claims 28 and 111 as obvious over Basel, et al., the Examiner has clearly acknowledged that:

> "Basel et al. do not clearly teach a plurality of ribs formed on an exterior periphery of the skin as claimed."

The Examiner then goes on to attempt to develop a case of *prima facie* obviousness by concluding:

> "therefore, it would have been obvious to one skilled in the art at the time the invention was made to provide a suitable element, such as ribs on an exterior periphery of the skin of the hearing aid, in order to provide protection against cerumen or a hearing aid vent." (page 6, Numbered Section 12 of Office Action)

The above conclusitory statement is not in keeping with the requirements of the Federal Circuit or the rules or the Patent Office in propounding a *prima facie* case of obviousness. The

Examiner has failed to identify any teaching, suggestion or motivation in Basel et al. so as to modify Basel et al. to make claims 28 or 111 obvious. Indeed, in view of the fact that Basel et al. teaches the removal and non-use of the exterior skin 22 once the material 23 has hardened, one of skill in the art would never make the modification proposed by the Examiner. This is clearly a case of hindsight reconstruction where the applicant's disclosure has been used improperly as a roadmap to attempt to create a *prima facie* case of obviousness. For these additional reasons, claims 28 and 111 are also allowable.

For all of the above reasons, none of the pending claims are anticipated or made obvious by Basel et al.

In numbered section 10 of the Office Action, the Examiner objected to claim 21 pursuant to 35 U.S.C. §112, 2nd paragraph due to alleged indefiniteness. In this regard, the Examiner opined, last two lines of page 4 of the Office Action that the limitation of "the skin does not exhibit sufficient rigidity to be insertable into the user's ear canal" in lines 2-3 "it is vague because it is not clear what the limitation is". It is submitted that the disclosure and claims of a patent application, and subsequently, the issued patent, are directed to those of skill in the art who can be expected to read the claims in light of the specification. In this regard, the subject limitation is made clear in view of the text starting at page 12, line 8 and extending through at least line 3 of page 13 of the pending application. The noted text refers to the following:

> "In the absence of spine of vent tube 22, hearing aid 10 will be difficult to insert into the ear canal. Soft shell 12 and matrix 18 deform causing receiver 16a to move toward modular face plate 20 and abut microphone 16a-2, see Fig. 5A-3. This distorts the shape of skin 12 and stresses wiring 16a-3 between processing circuits 16b and the output transducer, receiver 16a. Hence, the shell 12, even in the presence of matrix 18 and internal components such as receiver 16a and processing circuits 16b readily deforms in the presence of forces FU, FC." (page 12, lines 17-23 of specification)

The above as well as the other text noted above and figures referred to therein clearly informs one of skill in the art as to the characteristics of the formable shell 12 which "does not

exhibit sufficient rigidity to be insertable into a user's ear canal" as required in claim 21. Thus, it is submitted that claim 21 does in fact comply with the requirements of 35 U.S.C. §112, second paragraph when considered in the light of the specification and figures of the subject application. It is requested that this objection be withdrawn.

Responding to Numbered Sections 8 and 9 of the Office Action filed herewith are terminal disclaimers relative to U.S. Patent No. 6,393,130 and 6,584,207.

Also attached hereto is a proposed drawing correction, marked in red, relative to numbered Section 7 of the Office Action. In this regard, an additional paragraph has been added to page 20 of the specification. No new matter has been added.

The withdrawal of claims 118 through 126, numbered sections 3, 4 of the Office Action was improper and not in keeping with the rules of practice, specifically 37 C.F.R. §1.141(a). Rule 141 specifically provides that:

> "more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all of the claimed species and all of the claims to species in excess of one are written in dependent form."

Claims 118-126 depend from independent claim 104. Claims 118-126 are thus properly directed to other species of the invention.

It is clearly improper to withdraw from consideration, dependent claims such as 118-126 which depend from a pending independent claim which is being examined. This is not the situation contemplated by either 37 C.F.R. §1.142(b) or MPEP §821.03 as referred in Numbered Section 4 of the Office Action.

37 C.F.R. §1.145 only permits such withdrawal from consideration where the claims are "directed to an invention distinct from an independent of the invention previously claimed."

This is not the case here. The withdrawn claims are all dependent form claim 104, which is being examined. Hence, they are not "independent of the invention previously claimed". Further, they are not "distinct" therefrom in that this is not a situation where there is a combination or a sub-combination or two different sub-combinations which are usable with each other. Nor is this a circumstance of a process and apparatus for its practice, or a process and a product made thereby. MPEP §802.01. Therefore, it is requested that the withdrawal of claims 118-126 be reversed and those claims be allowed for at least the same reasons as set forth above relative to claim 104.

Allowance of the application is respectfully requested.

Respectfully submitted,

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